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## 2 Application of Plastics in Medical Devices and Equipment

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This chapter will present a look at the medical device market with a particular focus on the materials of construction of devices and what we can expect in new products looking ahead. A deeper look at some other trends that have an effect on the direction of the medical device industry will be done. Finally, consideration will be given to a number of global factors that can have dramatic effect on our industry.

### 2.1 Device Industry Overview

The medical device industry has roots in the foundation materials of glass intravenous (IV) bottles, rubber tubing, and metal operating room instruments. The development of plastics in the 1930s, 1940s, and 1950s enabled the development

of medical devices that overtook and eventually replaced the foundation materials with newer and better materials such as polyvinyl chloride (PVC) for IV bags and tubing, silicone tubing for catheters and balloons, polyolefins for trays and bottles, and fluoropolymers for IV catheters. New polymeric material developments continued to allow a virtual explosion of devices and implements which were able to rely on the excellent properties that were offered by engineering polymers, newer commodity plastics, and improved processing technologies.

As the availability of new products continued to grow, the health-care industry grew as well and by offering life-giving procedures, led to improved health of the population in general. New drugs such as sulfa drugs, penicillin, the Salk polio-vaccine, and insulin all led to the health-care industry being

able to provide treatments to a great segment of the overall population, not just the elite, privileged classes or the wealthy. The wide availability of good quality, clean, sterile products at prices that were not absurdly high allowed the widespread growth of smaller hospitals and clinics where the sick and injured could receive medical treatment.

The device industry has grown together with the population expansion following World War II and with the globally expanding baby boomer generation. New technology in materials science, processing, and assembly, and in the health-care community combined to make the global medical device market a \$200 billion market in 2008. With a growth rate of 8%, by 2012, the size grew to over \$250 billion. The United States is reported to consume between 45% and 47% of the world market for medical devices, while US exports account for an estimated \$37 billion, with these products going primarily to Europe (46%) and Japan (12%). The 42% which goes to the rest of the world accounts for approximately 57% of US exports and this segment is growing more rapidly than both the European Union (EU) and Japan as so-called third world or emerging economies begin to consume the basic health-care products for their demanding needs of their populations.

Analysis has shown that the “BRIC” countries of Brazil, Russia, India, and China will be those markets that have the most rapidly growing demand for medical devices. Growth of health care in other parts of the world such as Eastern Europe, the Middle East, and Africa will follow. However, as in any economy, before the general population can be served with a comprehensive health-care system in a country, there needs to be a stable political environment and where basic needs of food, clean water, sanitation, and shelter are available.

Another requirement is the establishment of a health-care delivery infrastructure. It does no good to ship sophisticated or even basic medical devices to parts of the world that have a need for these products if there is no one available to monitor, distribute, and administer the products and to provide for their proper use. Surgical suites cannot effectively operate for more than just the short term in temporary shelters or make-shift buildings. It will take a commitment on the part of the local governments to begin to provide facilities

and utilities to the health-care professionals that would then begin dispensing care to the local population.

Evidence of this process is the rebuilding of the war ravaged country of Viet Nam in the late 1970s and 1980s. By no means has this part of Southeast Asia emerged into a sophisticated health-care provider but once stability had been restored, the infrastructure was slowly developed in the population centers, and hospitals and clinics were then able to provide care to their citizens.

## 2.2 Health-care Trends

Any review of the medical device industry will quickly reveal that several trends are emerging that are shaping the device industry. Three that I will note are:

1. The trend toward minimally invasive surgeries (MIS)
2. The growing popularity of alternate site treatment
3. A strong movement toward prevention vs. treatment of disease.

### 2.2.1 Minimally Invasive Surgeries

Not many years ago, when a heart patient presented with blocked or restricted arteries, the only course of treatment was to do open heart surgery or coronary artery bypass graft (CABG) surgery. This complicated, expensive, and traumatic surgery required the blood to be circulated by way of blood pumps and tubing through oxygenator devices, while the heart was taken “off-line” allowing the surgeon to replace the occluded blood vessels with harvested vessels usually from the patient’s leg. These new vessels were grafted to the heart muscle and bloodstream to “bypass” the occluded vessels effectively restoring normal flow of blood to the heart muscle. The “bypass” surgery required cutting and spreading open the chest of the patient allowing the surgeon access to the heart. Often the recovery from all the steps taken to gain access to the heart muscle took longer than the recovery of the heart surgery itself! Recovery times were counted in weeks in the intensive care unit and hospital rooms and months

more at home before normal activity could be resumed.

The development of the heart catheter that was able to deliver a vascular stent or scaffold changed the landscape for treatment of blocked arteries. Cardiovascular surgeons were suddenly able to access the occluded artery using these balloon catheters which were inserted through the femoral artery in the area of the groin. Newly developed imaging technologies gave the cardiovascular surgeon a way to accurately position and deploy a stent in the occluded artery immediately restoring the normal flow of blood through the once occluded artery.

Other products such as multiple instrument access ports allowed for minimally invasive surgeries to be performed within the peritoneal cavity through a single incision in the abdomen. The port would be positioned through the incision and by inflating the cavity using a process called “insufflations,” and the surgeon could view inside the body using an endoscope or viewing instrument. The surgeon could then perform procedures such as biopsies, appendectomies, gallbladder procedures, hernia repair, and hysterectomies without the need to open the abdomen beyond the one small incision. Recovery times are greatly reduced, there is far less blood loss, the risk of infections and other complications from the open procedures have been drastically reduced, and the added benefit is that the cost of health care has also dropped.

These new minimally invasive surgical techniques, however, have also led to the development of many new products designed to improve how the procedures are performed. It seems that every medical device company has introduced its own version of the access port and the procedures carry unique names such as Natural Orifice Transluminal Endoscopic Surgery (NOTES). The benefits of MIS are obvious and the amount of new development being done to extend the procedures that are possible with MIS continues to grow.

Orthopedic procedures are possible using MIS with arthroscopy for joint exam and repair being the most commonly used joint repair procedure. Total joint replacement of the hip is now possible with products that rely on endoscopy. And linking this technology with computer-driven robotics has enabled the development of the DaVinci remote surgical system. This takes the possibility of alternate site health care to a new level with the surgeon

being able to be remotely located from the patient on whom the procedure is being performed.

### ***2.2.2 Alternate Site Treatment***

The norm had for many years been that anyone sick or requiring medical assistance would go to the doctor and likely end up in the hospital for care and treatment. With the emergence of chronic illnesses such as renal or kidney dialysis, it became clear that quality care could be offered to special segments of the population in specially designed outpatient facilities. Doctors' offices became locations where X-rays could be taken, broken bones treated, and minor surgical procedures would be performed. Emergency clinics became satellite locations for the general hospital in the area, and these clinics were staffed with doctors and nurses that in many cases enabled patient care that eliminated the need to even go to the hospital.

Hospitals continue to be the place for major surgeries, intensive care units (ICU), trauma care, and specialty care such as in burns units. Patients that were mobile and otherwise active, however, could get their chronic care by way of the outpatient clinics in conveniently located sites near their homes and communities. Oncology patients could receive the twice or thrice weekly IV infusions at the alternate site, and rehab services, which only had been available at the hospital, were now offered at locations other than the hospital.

The trend to seek health care at locations other than the hospital brings other opportunities for the medical device industry. Products used at the alternate site must be the same good quality as offered by the hospital, but in some cases since the health-care providers may not have the same level of experience as the hospital staff, the medical devices and equipment need to be made so that new or inexperienced users can reliably and effectively use the product as intended. Products for use in the non-hospital settings should have ease-of-use built into them and the instructions for use must be easy to read and understand.

One final alternate site trend is the tendency to take health care to the home. The cost of health care and the increased restrictions by insurance providers is leading to shorter hospital stays, earlier discharges, and a greater reluctance to admit patients, instead often opting for outpatient treatments. This trend places a greater burden on the

family of the patient or requires a mobile health-care provider to visit and look in on the condition of the patient and sometimes administer medications, therapy, or treat recovering wounds.

When the burden of responsibility falls on the family, medical products and devices must be designed and made so that the non-professional care giver can understand clearly how to use them easily. Often an elderly spouse is the only person available to care for a loved one and if medication containers are difficult to open, if devices are hard to hold and operate, or if the instructions are not clear, it becomes a challenge for the provider to comply as they should.

So to summarize, medical device companies need to consider how their products will be used and by whom. As alternate site delivered medical care becomes more commonplace, products must be made so that even complicated care procedures can be done without a chance of compromising the health of the patient or the care provider.

### ***2.2.3 Prevention vs. Treatment***

One final trend that is worth considering in this review is the trend toward prevention of disease or health problems by early diagnosis of a problem and early treatment. Current improvements in diagnosis of a patients' condition can enable the physician to detect the early onset of a problem condition whether that condition is high blood sugar levels pointing toward diabetes, chronic high blood pressure pointing toward heart disease, or the early onset of prostate cancer as indicated by increased prostate specific antigen (PSA) levels.

Effective diagnosis can be done using small samples of blood or urine or other body fluids. These tests are becoming less expensive and therefore are more likely to be done and reimbursed by insurance programs thereby leading to better monitoring of patients' health over the course of their life.

Other more sophisticated diagnostic procedures involve more intensive testing and analysis such as genetic screening. In the case of inherited genetic mutations, genetic testing can detect a patients' likelihood of developing breast cancer. Genetic testing can also determine if a patient has the inherited precursor to breast cancer leading to early and continuous monitoring of their health or leading to those patients seeking preventive surgical intervention such as mastectomies.

Earlier detection of health problems allows earlier treatment of the condition and in many cases the treatment will prevent the full onset of the diseased condition. The patient can avoid the effects of a fully engaged condition and with early treatment the disease may be completely avoided.

This trend toward disease prevention rather than treatment points to the ever-increasing demand for diagnostic products. From instruments that perform the analysis to the containers and reagents that are consumed during the testing to the devices that are used to collect the blood, fluid, and tissue samples, all these require carefully designed and manufactured medical devices. This is a very rapidly growing segment of the industry.

## **2.3 From Legacy Materials to Advanced Specialty Polymers for Devices**

The need for high-quality medical devices has been explained in this chapter, but the construction of these devices has not been addressed. The emergence of PVC, polyolefin polymers, and other traditional commodity plastics was briefly touched upon in Section 2.1. But with the assessment of the trends described in Section 2.2, the full range of medical devices from single use disposables (SUDs) to reusable devices to hardware (e.g., pumps, ultrasonic instruments, heart monitors, and even MRI equipment) all require materials of construction designed to meet the needs of the product and survive the rigors of use, either single use or long-term use. The majority of products made for the device industry are made from commodity polymers or readily available, inexpensive polymeric materials. As the requirements for components or new medical device requirements push the limits of the most generally used materials, new materials are selected that meet the more rigorous requirements.

Examples are higher temperature polymers designed to survive continuous use at elevated temperatures or a polymer that can withstand exposure to aggressive cleaners or solvents now being used to reduce the frequency of hospital acquired infections (HAIs) or materials that can be precisely molded into micro-sized parts with very high tolerance requirements while also surviving the rigors of use.

The primary materials in use continue to be the four mainstay polymers: of polyvinyl chloride (PVC), polypropylene (PP), polyethylene (PE), and polystyrene (PS)—with styrene copolymers of ABS and SAN. But more devices are being made from additional materials which provide improved performance. Some of these materials are PC (polycarbonate), polyethylene terephthalate (PET), or any of the many available polyesters, TPU (thermoplastic urethane), TPE (thermoplastic elastomers), and polyamides (PA, both traditional nylons and amorphous nylons).

With newer devices constantly being developed, the need for new components and new specialty materials continues to increase. At the same time, new polymers and polymer formulations available for use continue to grow. Suppliers are continuing to develop new options that better meet the need for improved performance, allow the use of new technology, and extend the reach of the latest therapies.

An example of a relatively recent new material entering the device industry was the family of materials called liquid silicone rubber (LSR). LSRs allowed component products made from this silicone elastomer formulation to replace the more expensive and more difficult to process gum rubber silicones or different two-part silicone compounds that also were not as easy to process as the LSRs. These new formulations have the superior properties that make silicone so desirable for the medical device industry while also having the ability to be easily injection molded into quality parts. These materials rival the best TPEs as well as the traditional silicone rubber formulations.

There have been new polyolefins developed that can be used as tubing materials for applications which make PVC or silicone unacceptable. These softened olefins have even been considered as PVC replacement materials for such applications as steam sterilized fluid containers. Instruments that must be repeatedly cleaned and sterilized, sometimes multiple times in a day such as dental instruments, can now be made from high-performance polymers such as polyether imide (PEI) or polyether ether ketone (PEEK) polymers. Even some of the commodity polymers are being improved, for example, linear low density polyethylene (LLDPE) is now offered with better clarity, improved heat seal temperature range, and superior seal strength. All these

improvements result in better medical devices often at lower manufacturing cost.

## 2.4 Driving Trends Leading to New Material Requirements

The earlier assessment of trends in health care led to a review of why certain areas of the industry are growing and showed why specific types of medical devices are being developed to meet the needs of the most recent industry trends. This section focuses on the factors that directly affect the devices that are being designed and made to serve the needs of industry. There are four trends listed below that cover how the industry from the suppliers to the converters to the final device manufacturer are all responding to the needs of the ever-evolving industry.

### 2.4.1 Functionality

Components of devices must be made in a way that the resultant device or instrument can be used without an operational problem. Newer polymers allow the design of multiple features into one molded component that, for example, may be able to replace metal components or multiple smaller parts. Product redesign and design for manufacturing with the latest materials can bring improved performance to the medical device while reducing the cost of the device.

An example of this is the ability to preprint labeling or bar code information on a film that is then fabricated into a laminate for final manufacture into a fluid container. The critical information contained on the film is printed on an inner layer of the laminate and then sandwiched between outer layers of the laminate. The printing is protected from abrasion or exposure that might damage the printing as it would a label that is printed or affixed to the outside of the container after fabrication. Only with the ability to make dimensionally controlled films, and with the availability of polyurethane adhesives suitable for medical devices, is this technology possible.

Other new adhesives developed to improve the bonding of plastic components can offer better joints while also eliminating the use of volatile solvents. Ultraviolet light-cured adhesives can be used to bond a tubing to a connector while giving

superior bonds and a controlled method of application and cure as compared to other methods of bonding. This type of adhesive also enables the use of automation for certain products and with the cost of manufacturing such a critical part of making any medical device, the possibility of eliminating labor by using automation is a meaningful benefit.

Medical devices continue to get smaller and the complications related to making these ever smaller devices and their components present a challenge for both the material and the processes used to make small or micro-components. Multifunctional devices such as the Pill Cam rely on extremely tiny components but together they offer a product that gives remarkable results improving the diagnosis of the condition of a patient's colon.

The Pill Cam is designed to be swallowed by a patient needing a colon exam. Once swallowed, the Pill Cam will track through the body, eventually passing through the entire length of the large intestine, and is then eliminated from the body. During the transit, which is reported to average about 17 hours, it takes two pictures or images of the walls of the large intestine every second. These images are transmitted wirelessly to a receiver outside the body for later analysis. Any irregularity or polyp or lesion can be detected and diagnosed by the surgeon who previously relied on the examination of the colon using a colonoscope. The older procedures called colonoscopies are done on mildly sedated patients in a hospital examination room. This invasive procedure often requires two or three health care professionals and may take up to an hour to complete. The Pill Cam provides this problem by viewing of the entire length of the colon. The resultant set of information available to the surgeon is so large that it often requires retraining to enable the health-care professional to read and understand the dataset obtained from the Pill Cam. This new technology improves the diagnosis accuracy, helps eliminate false positives, or the need for investigatory biopsies, but also is more cost effective and from a patient perspective, a far more comfortable option to the colonoscopy.

One final example of a polymer allowing the improvement of patient care by the use of improved materials and manufacturing technology is the move toward individual specific product labeling that the US FDA (Food and Drug Administration) is implementing. Only with the availability of materials, techniques and equipment can there be a

system of UID (unique identification) for devices in the market. Low cost but reliable options will make possible improved device tracking for patients having long-term implantable products or devices.

### **2.4.2 Compatibility**

The term compatibility can be defined in a couple of different ways. The first way is the compatibility of one material with another material which would allow, for example, reliable overmolding of one material onto another material and expecting good adhesion between the two. One example is a housing that needs to be watertight. It incorporates an overmolded sealing gasket directly onto the housing where it would be joined and sealed to the other half of the housing. Unless the materials can be selected each having compatibility with the other, the seal might not perform as expected.

In another example, overmolding was used by an orthopedic instrument company not only to reduce the weight of the tools such as bone hammers and chisels, but also to enhance the performance by giving the user a better gripping surface. These tools are most often used by the surgeon who is gloved and the gloves are not always dry. By using a material that provides improved wet grip characteristics, the reduced weight of the tool, the ergonomic design for finger gripping, and better wet grip made these tools award-winning products. And it was the use of properly selected TPEs that allowed these products to be made effectively. The instruments are repeatedly cleaned and sterilized. The proper selection of the material for compatibility with the process is one of the biggest challenges with this product.

The other use of the term compatibility which is being covered in this review is perhaps more properly termed biocompatibility. But specifically what is meant in this context is the compatibility of the plastic medical device with the health-care need. There are medical devices now available that can be used as joint replacement materials. These materials have been found to provide better long-term outcomes for patients instead of the stainless steel (SS) materials of construction. The implant is made from PEEK polymer that is selected to better match the normal flexibility of the bone into which the implant is secured. When an SS implant is used, the adhesion between the implant and the bone over an extended period of time tends to loosen

because the bone has a small amount of flexibility, whereas the SS implant does not flex. This lack of flexibility is called “stress shielding”. But using the PEEK polymer as the implant stem, the polymer has close to the same flexibility as the bone and there is a reduced tendency for the implant to loosen over time. This compatibility between bone and polymer makes a more effective medical device and one that will allow better long-term outcomes especially as the average length of implant gets longer with an increase in life span of the general population.

One other similar trend that is dictating the selection of a new medical device material is the concept of resorbability. Resorbable polymers are the newest family of polymers getting serious attention as new products made from them enter the scene. Resorbable polymers have long been used for internal sutures to eliminate the need for a second surgery to retrieve the sutures positioned somewhere under skin. There is an ever-increasing list of new uses for these polymers which include polylactic acid (PLA), poly glycolic acid (PGA), polycaprolactone (PCL) polymers, and all the various copolymers in between. Devices made from these resorbables, when the material is properly selected, provide the mechanical integrity and strength to allow recovery of the patient. But after the bone or tissue heals, the natural process of the body will begin to digest and dissolve the implant. Examples of this family of polymers being used are for bone screws, plates and pins, tissue anchors, sutures, and one of the most recent developments for cardiovascular stents. In theory, any foreign material positioned in the body for an extended length of time has the potential to cause some unexpected complication. But if the long-term implant is made from a material that will gently be digested and metabolized and excreted, there is no foreign body left behind to cause a problem. For this reason, there is a great deal of attention being given to this new class of polymeric materials and the list of new products which are based on these bioresorbables will continue to grow.

## **2.4.3 Cost**

### **2.4.3.1 Material Costs or Process Improvements**

There are few products in the medical device industry that have the luxury of freedom from the

cost of material and final product cost in order to be a viable product. The large majority of products are very price sensitive and any way that costs for the final product can be reduced is continually being considered. If for example by using a material with higher temperature properties the time it takes to sterilize the product can be reduced by using a higher sterilization temperature and not affect any other aspect of the product, this would be a very favorable option. The length of time to sterilize and ultimately manufacture the product would be reduced leading to significant cost savings. Large volume products such as IV bags would benefit from such a material improvement.

Any material that can be offered to a device manufacturer that has the potential to reduce the cost of manufacturing can bring an advantage to that product. It could be as simple as easier injection moldability or faster cycle times or something that would help reduce the reject rate or reduce scrap; all these would be considered worthwhile investments to qualify a new material for use in a long-term, high-volume product.

### **2.4.3.2 Light Weighting**

Some products could be made for lower costs and result in savings based on light weighting of the product from both a materials consumed standpoint and reduced transportation costs. The example of the orthopedic instruments mentioned above shows that light weighting or reducing the overall weight of the product gives a functional advantage to those products allowing greater ease of use and resulting in less fatigue in the hands and arms of the surgeons who use these tools often on several patients in a row during their day of surgery.

Light weighting can bring down the ultimate cost of disposal of the used medical devices, not an insignificant cost of doing business in this industry. Smaller product footprint reduced size of packaging and improved shipping and handling costs all result from light weighting or downsizing the medical device as long as there is no commensurate loss in quality or functional performance.

### **2.4.3.3 Commoditizing Materials of Construction**

This last subcategory of trends that helps drive material costs down is a trend to expand the products that a company manufactures but making the

components and devices using a common polymer or raw material. As the consumption of a particular polymer grows, the purchase pricing is improved. Additional advantages are that instead of using multiple types of plastics, if one plastic can effectively satisfy the requirements across multiple product lines, then the qualification of new materials is eliminated, there is no need to stock multiple grades or different types of plastics, and the need for incoming testing all those various materials goes away.

All this points to the need for material suppliers to offer materials that have the properties needed for products. If one material can survive exposure to all three of the most common sterilization methods, steam, ethylene oxide gas, and irradiation, then this material would have an advantage over a polymer that is suited to only one or the other or two of the three methods, all else being equal.

One additional consideration for this recommendation is to try if possible to build products on the one material that works. This is that a company becomes familiar with how a material is processed, how it needs to be assembled, and how the product works with that material. This collective knowledge will result in better product, more efficient manufacturing operation, and a reduced product cost.

#### **2.4.3.4 Technology Innovations**

New device design and processing technologies can improve products and result in better market share and reduced product costs. Companies that stay current with the latest technology will have the advantage over others that don't. Take for example the move from gated molds with sprue and runner systems to hot runner systems. The cold runner systems generated scrap with every shot that needed to be either discarded or reground and used. Hot runner systems eliminated that loss of material.

Vision systems can be installed on manufacturing cells that provide 100% checking of product to eliminate the concern that one of the products may get into the marketplace that is out of tolerance or otherwise unacceptable. Robotics are now available to move product from one place to another thereby eliminating the need for human handling or other random conveyance systems. This helps keep the component or assembly or device cleaner, free from contamination, and allows for the exact

location of that product. Knowing the location of a part allows subsequent steps to be taken in the manufacturing of that product from placing it into a tray, putting a critical label on the product assembling it into a product or packaging it.

By using the latest technology available for manufacturing the medical device, the best possible product will be offered to the customer. Micro-molding, two shot molding, and metal injection molding are all new process technologies that can affect a product and drive that product to the front of the line. Each new development in technology will put new requirements on materials but in the end, these innovations will enable the development and introduction of game-changing new devices.

#### **2.4.4 Ecological and Environmental Concerns and Influence of the Consumer**

The final trend that drives new material requirements to be addressed here is the influence of the consumer especially in the current climate of eco-consciousness and environmental awareness. Gone are the days of medical devices being bought based on the personal relationship of the doctor and the company sales representative. No longer are products used because of their appealing color or because of the reputation of the supplier. Buying decisions are being influenced by patients, families of patients, hospital committees that evaluate the products, stockholders or investors of the buying groups, and these days, even politicians are involved. Most medical device manufacturing companies are aware of the need to be environmentally responsible in design of their products, how the products are being manufactured, how these products are used and even how they are discarded after use.

Technologists responsible for the design and manufacturing of medical devices must continue to use the latest materials and process technologies to offer the best products possible. The recent evolution of antimicrobial materials shows a materials technology that at least on first glance seems to have potential to benefit the medical device industry; especially if it actually does reduce the spread of infectious pathogens. The idea of antimicrobial sounds good and is quickly adopted by the general public as an improvement (be it real or just

perceived) and it will be up to the device manufacturers to decide on the best way to incorporate such new technology into their products.

To summarize this subcategory of the influence of the consumer on medical device materials, it is important to recognize that there are other players in the scheme of health-care business. Those that will have a significant influence on products that will be a success in the marketplace and those that will not. The consumer of today has information at their fingertips that allows them to be a better informed health-care consumer and empowers them to request and at times even demand the type of product they feel is best. It will benefit the device industry if this influence on products is carefully considered.

## 2.5 Market Factors Affecting the Industry

Behind the scenes of the medical device industry and health care are the continuing investigations to ensure safety of the general population. Sometimes the investigations are done at universities, sometimes they are done by companies or their competitors and sometimes independent researchers conduct the investigations. Often there are governmental-funded investigations or studies done by activist groups. But no matter who does the investigation and sometimes it does not even matter if the study is done well or not, the results usually will affect the industry, and products in the health-care market will be affected.

### 2.5.1 Concerns Over DEHP and Sometimes Even PVC

If it were not for the improved ability for blood storage in diethyl hexyl phthalate (DEHP) plasticized PVC coupled with the low-cost superior performance of PVC medical devices, it is not likely that this industry would continue to rely so heavily on this controversial polymer. But flexible PVC is quite a remarkable material meeting so many important needs of the industry from providing safe high-quality inexpensive IV fluid products for patient care, to tubing for conveying the IV fluids, drug therapies and blood, and finally blood collection and storage. There continues to be a drum beat throughout industry alleging that phthalate

plasticizers and specifically DEHP poses a danger to those exposed to it from these PVC medical devices. Thousands of studies conducted over more than 40 years of its use have not found reason to stop using f-PVC (flexible polyvinyl chloride). To be precise in this explanation, the studies have not found a problem; but as in any investigation, it is virtually impossible to prove that PVC is safe under all conditions and at every exposure level for every possible population segment. Proving a negative is virtually impossible. At best, industry experts can point to the lack of data showing harmful effects, can further indicate that for billions of uses and in millions of patient infusions, there has not been shown to be any harmful effects in patients exposed to DEHP plasticized PVC, even those listed under the special concerns listing by the FDA. Chemotherapy patients, chronic hemodialysis patients, patients receiving lipid emulsions, and premature infants were all categories of patients that may be more susceptible to adverse effects of high-dose exposure to DEHP. Nevertheless, if alternative materials are available, and if the practitioner were to have concern related to DEHP exposure, it would be a simple matter to use the other materials. But if the choice is between using DEHP plasticized PVC and not giving the patient infusion therapy because alternative materials are unavailable, it would be irresponsible to withhold treatment.

There are strong feelings about this issue and the influence by those holding these opinions has been successful in causing major companies and buying groups to choose to avoid using products that are based on f-PVC. As yet the feedback has not been available regarding the compromise of properties and the effect on patients when using newer materials or the effect of the additional costs of the newer products. It was originally reported that there would be significant savings to the users by switching to the newer materials. This assertion has not yet been verified.

### 2.5.2 Bisphenol A

Another external factor affecting the medical device community are concerns raised by researchers and voiced in the last five years related to bisphenol A (BPA) coming from plastics. This chemical, a building block for making polycarbonate (PC) plastic, is extracted in minute amounts from containers under certain conditions and

potentially finds its way into humans from either certain beverage containers or medical devices which use PC in their construction. The level of BPA found in the bloodstream of mothers and newborn infants was reported to be detectable and higher than expected and the inference was that the chemical came from medical devices. The reason for the concern is that BPA is reported to have hormone-mimicking properties and is therefore said to be a chemical to which humans should not be exposed. The reality of the hazard is not confirmed but in a move toward caution, baby bottle and sport drink container manufacturers have changed the material from PC to alternative materials.

A review of the use of PC in medical devices shows that it is used primarily in connectors and fluid directing components such as manifolds and catheter hubs. The potential exposure of the IV fluids or blood to the PC surfaces is very short duration and the surface area of contact is extremely small leading most device engineers and toxicologists studying the situation to have little concern. The mood of the general public however has caused enough of an uproar that some companies are seeking PC alternative materials. As yet, this situation has not been fully played out.

### **2.5.3 The Need for “Green”**

The consumer is much more aware of the effects of products, including medical devices on the planet, and would like to see products made with renewable resources that reduce the dependence on non-renewable materials. With this in mind, many companies are looking for ways to include renewable materials in their product-line and slowly reduce the amount of non-renewable plastics on which they rely.

It would serve the medical device community well to understand the materials available from companies such as NatureWorks, Metabolix, and Braskem as new products are developed. And every effort to follow the 3Rs—Reduce, Reuse and Recycle—would be to the advantage of every product manufacturing company.

### **2.5.4 Globalization of Markets**

Populations across the face of the earth are becoming more aware of and seeking basic levels of medical care that have become the norm in

developed nations. The availability of relatively inexpensive transportation costs makes it possible to expand health-care services to places unreachable only 20 years earlier. With a willing and invested government, basic health care needs can be met with commodity medical devices. As the need becomes apparent, local efforts by local companies in these emerging areas are working to establish manufacturing for medical devices primarily for in-country use.

### **2.5.5 Globalization of Manufacturing**

Multinational companies have been very successful in manufacturing product in parts of the world where low cost labor is available. That product is then shipped to where the market demand exists. Several factors are changing this situation including the rising cost of labor, even in the most remote parts of the world, increasing energy costs affecting transportation of product, and the growing demand for product in every corner of the world. As local manufacturing is established, distant transport is reduced or eliminated. However, the level of quality is expected to be the same as products made in the primary manufacturing plants and if it is, market growth will match the increase in evolving economies.

#### **2.5.5.1 Energy Costs**

A major factor affecting globalization of manufacturing is the cost of energy. Transportation costs have already been mentioned as having an influence on where medical devices are made, but another factor is the cost of both raw materials and energy to produce the final product. Further considerations are the requirements for support of the remote operation from corporate headquarters.

### **2.5.6 Global Influences**

#### **2.5.6.1 Infectious Diseases (MRSA, SARS, H1N1)**

Several other factors to consider in the global assessment of health care and the medical device industry are the effects of contagious diseases such as avian bird flu, SARS (severe acute respiratory syndrome) and MRSA (methicillin-resistant *Staphylococcus aureus*). These contagious diseases

and others can rapidly spread around the world affecting countless numbers of the global population. Products are needed that can help stop the spread of any outbreak and treat patients that contract the disease. Part of the problem is that rarely is any attention given to this problem until there is actually an outbreak. Preventive measures are difficult to justify but unless done, the after-the-fact response is usually too little, too late.

#### **2.5.6.2 Economic Pressures**

A final market factor that is worth mentioning is the global economic situation. No longer can one country's economy be considered independent of other countries since there has developed in most parts of the world a global interdependence. When the EU falters, it affects the economy in the Middle East and Asia as well as in the United States. Governmental elections often cause market swings across the world and when conflict or war breaks out, the ripple effect can be seen throughout the

world. It is with this in mind that medical device companies now are encouraged to keep a global perspective even if their primary markets are not spread across multiple continents. Companies are advised to be aware of what is happening around the world in order to stay current and relevant in meeting current and future demands of the health-care needs of people everywhere.

## **2.6 Conclusion**

It is essential that any review of the medical device market includes not only the materials of construction of existing medical devices but also takes into account new materials, new processing technologies, and the ever-changing needs of the marketplace. We exist in a global economy that is constantly changing and only by staying aware of and up to date on influences that affect our industry can a company keep their product mix at the forefront of health-care delivery.